

**K211871 FAICO Dental Implant System and CAD/CAM
Abutments**Nov 18, 2021
154 days to decisionK211871 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k211871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 17, 2021
Decision date	Nov 18, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Faico Medical, LLC
Location	Boca Raton, FL, US
Contact	Hernan Dario Fernandez
510(k) history	3 submissions · 3 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Arazy Group
Contact	Raymond Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211871/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026